

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

THIS DOCUMENT RELATES TO:

*Gaston Roberts et al. v. Zhejiang
Huahai Pharmaceutical Co., et al.,*

Case No. 1:20-cv-00946-RBK-JS

MDL No. 2875

Honorable Renée Marie Bumb
District Court Judge

**DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION TO EXCLUDE
OPINIONS OF GREGORY DIETTE, M.D., M.H.S.**

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INTRODUCTION

Dr. Gregory Diette is a highly qualified physician and epidemiologist who opines that valsartan containing trace amounts of NDMA taken at low-level doses is not capable of causing liver cancer, including Mr. Roberts' hepatocellular cancer ("HCC"). Plaintiff does not challenge Dr. Diette's qualifications or the reliability of his methodology. Rather, Plaintiff solely argues that Dr. Diette's case-specific general causation opinions are "untimely" under Judge Kugler's prior scheduling orders. (Pl.'s Br. at 5.) Plaintiff's motion fails on multiple levels.

First, Plaintiff does not cite a single order from Judge Kugler precluding the parties in this MDL from presenting case-specific general causation evidence at individual personal injury trials. To the contrary, Judge Kugler expressly recognized that the general causation question in personal injury cases is "too idiosyncratic" to deal with on a global basis and specifically contemplated the presentation of new case-specific general causation testimony in personal injury trials. Plaintiff's argument to the contrary is foreclosed by her own designation of a new witness, Dr. William Sawyer, whose report reviews the general causation epidemiology, including a new scientific study—Mansouri 2022—that was published long after the global *Daubert* proceedings in this MDL. Dr. Diette was expressly designated to respond to Dr. Sawyer, which he does in his report. The fact that Plaintiff's counsel now seeks to retract Dr. Sawyer's general causation opinion in an effort to exclude

Dr. Diette cannot make Dr. Diette’s testimony untimely.

Second, any purportedly late disclosure of Dr. Diette’s opinions was substantially justified and harmless. The Third Circuit has emphasized that exclusion of expert testimony on timeliness grounds is an “extreme” sanction requiring a finding of bad faith. Plaintiff does not even address this requirement, effectively conceding that Defendants did not deliberately disobey any order. And although Plaintiff contends that admission of Dr. Diette’s opinions would result in “prejudice” (Pl.’s Br. at 5), that is not credible given that Dr. Diette seeks to rebut the opinions disclosed by Dr. Sawyer and Plaintiff has already deposed Dr. Diette about the substance of his opinions, belying any claim of unfair surprise.

Third, even accepting Plaintiff’s misreading of Judge Kugler’s prior scheduling orders, those orders should be reconsidered in light of significant new scientific developments—namely, Mansouri 2022, a study published long after the conclusion of the global *Daubert* proceedings, and one of only three studies that are relevant to the causation questions in this specific case.

For all of these reasons, Plaintiff’s motion to exclude Dr. Diette’s expert report as untimely should be denied.

BACKGROUND

General causation—i.e., whether NDMA at the levels allegedly contained in valsartan can cause liver cancer (or specifically, HCC)—is an important and highly

disputed question in this litigation. The admissibility of general causation evidence (whether valsartan containing trace amounts of NDMA can cause cancer generally) was originally addressed by Judge Kugler in a ruling issued on March 4, 2022, based on briefing and a scientific record that had been completed in July 2021. (*See Daubert Hr'g Order 1 Regarding Parties' Mots. to Preclude Test. by Expert Witnesses* at 1, Mar. 4, 2022, ECF 1958 ("Daubert Order"); *Case Mgmt. Order No. 22*, Nov. 25, 2020, ECF 640.) In a three-page order, the Court largely admitted the general causation expert opinions, repeatedly emphasizing that "[t]he jury is going to have to determine which of the[epidemiological] studies they think are important and which are not[.]" (Mar. 2, 2022 Hr'g Tr. 151:4-6, ECF 1959; *see also Daubert Order* at 2.) Before entering that order, however, Judge Kugler made clear that the general causation question in personal injury cases is "too idiosyncratic" to deal with on a global basis. (*See* Feb. 28, 2022 Hr'g Tr. 41:3-12, ECF 1946.) He also recognized that general causation experts "may need to take into account what is discovered [during fact discovery] in order to express their expert opinions[.]" (*See* Nov. 24, 2020 Hr'g Tr. 13:2-14:15, ECF 643.)

Important developments have occurred since the parties initially briefed the question of general causation in 2021. Most notably, Mansouri 2022 analyzed 1.4 million people from a national database of French residents, almost 1 million of

whom were considered exposed to valsartan containing NDMA.¹ The Mansouri 2022 authors found “a slight increased risk of liver cancer . . . in patients exposed to NDMA in regularly taken medications” (HR 1.12 (95% CI: 1.04-1.22)).² Oddly, that increased risk was not found in women (HR 0.90 (95% CI: 0.75-1.07)).³ In addition, the increased risk was limited to the poorest 20% of participants (social deprivation index quartile 5), suggesting that the study may have been affected by confounding.⁴ The authors also “found no evidence of a dose-response relationship between the daily dose of valsartan and the risk of any cancer by location.”⁵ In fact, the hazard ratios for liver cancer were higher in patients with lower doses. The authors concluded that “[m]ore research is needed” to “establish clinically relevant causality.”⁶

In light of Judge Kugler’s prior statements and the current state of the science, Plaintiff designated Dr. William Sawyer as an expert toxicologist in this individual personal injury bellwether case. Dr. Sawyer’s report includes a full causal analysis

¹ Imene Mansouri et al., *N-nitrosodimethylamine-Contaminated Valsartan and Risk of Cancer: A Nationwide Study of 1.4 Million Valsartan Users*, 11 J. Am. Heart Ass’n. 1 (2022) (“Mansouri 2022”) (Ex. 1 to Decl. of Nina Rose (“Rose Decl.”)).

² *Id.* at 1.

³ *Id.* at tbl S9.

⁴ *Id.*

⁵ *Id.* at 9.

⁶ *Id.* at 12.

under the Bradford Hill framework and concludes that there is “little or no debate that NDMA is a potent probable human carcinogen[.]” (Expert Report of Dr. William R. Sawyer, Ph.D. (“Sawyer Rep.”) at 79, Mar.10, 2025 (Rose Decl. Ex. 2).) Dr. Sawyer also includes a discussion of Mansouri 2022. (*Id.* at 39-41.)

In response to Dr. Sawyer’s report, and in accordance with the scheduling order entered in this case (*see* ECF 2982), Defendants timely disclosed Dr. Diette as an expert on April 10, 2025 (*see generally* Diette Rep. (Pl.’s Br. Ex. A)). Dr. Diette’s report includes an analysis of “the epidemiological literature regarding the hypothesized connection between allegedly NDMA-contaminated valsartan and the development of liver cancer” (including Mansouri 2022) and a Bradford Hill analysis focused on liver cancer. (*Id.* at 1, 7, 30-36.) Dr. Diette also specifically discusses the epidemiological findings with regard to HCC. (*Id.* at 10-11.) Importantly, Dr. Diette’s expert report contains a direct “[r]esponse” to Dr. Sawyer, explaining that “Dr. Sawyer never grapples with the very weak associations [with liver cancer] identified in only a subset of the relevant studies” and that he “largely ignores the lack of significant findings from Zheng 2021, the only dietary NDMA study to examine liver cancer, in favor of mixed findings from other site-specific cancers.” (*Id.* at 36-37.) Plaintiff deposed Dr. Diette about these opinions on May 8, 2025. (*See generally* Diette Dep. (Pl.’s Br. Ex. B).)

ARGUMENT

I. DEFENDANTS' DISCLOSURE OF DR. DIETTE'S OPINIONS WAS TIMELY.

Plaintiff's request to exclude Dr. Diette's opinions should first be rejected because the opinions were disclosed "in accordance with the deadlines set in the Court's scheduling orders." *See ABB Air Preheater, Inc. v. Regenerative Env't Equip. Co.*, 167 F.R.D. 668, 672 (D.N.J. 1996) (finding exclusion of expert testimony was improper and "there has simply been no violation of Rule 26(a)(2)" where "[i]t is indisputable that defendant disclosed its expert's opinions well before trial, and in accordance with the deadlines set in the Court's scheduling orders"). Although Plaintiff argues that Judge Kugler set "November 1, 2021 as the final deadline for service of defense expert reports on general causation" (Pl.'s Br. at 10 (citing ECF 640, 863)), the case management orders cited by Plaintiff merely set the deadlines for general causation discovery during the global phase of the MDL, which focused on whether exposure to NDMA in valsartan is capable of causing cancer as a general matter.⁷ Neither cited order remotely purports to preclude the parties from

⁷ (See, e.g., Case Mgmt. Order No. 22, Nov. 25, 2020, ECF 640 (order confirming deadlines for expert discovery in MDL); Case Mgmt. Order No. 23, Feb. 11, 2021, ECF 863 (order confirming Special Master's extension of certain MDL expert discovery deadlines); see also, e.g., July 29, 2020 Hr'g Tr. 46:1-7, ECF 636 (planning scheduling order for general causation expert discovery in the MDL); Sept. 30, 2020 Hr'g Tr. 49:4-25, ECF 586 (same); Revised Case Mgmt. Order No. 22, Jan. 11, 2021, ECF 726 (revised order regarding deadlines); Jan. 5, 2022 Hr'g

presenting case-specific general causation opinions from new experts during individual bellwether trials, including an expert to address whether exposure to NDMA in valsartan is capable of causing HCC, the specific cancer alleged in the *Roberts* case.

Judge Kugler also explicitly recognized that the general causation question in personal injury cases is “too idiosyncratic” to deal with on a global basis (*see* Feb. 28, 2022 Hr’g Tr. 41:3-12, ECF 1946), and he specifically contemplated general causation experts “tak[ing] into account what is discovered” during the case-specific phases of this litigation (Nov. 24, 2020 Hr’g Tr. 13:2-14:15, ECF 643).⁸ For this reason, Special Master Vanaskie refused to exclude certain plaintiffs’ general causation experts whose opinions were late, expressly permitting them to opine on general causation “in the specific causation phase of the [individual] case[.]” (July 28, 2021 Hr’g Tr. 12:13-21:17, ECF 1429.) Consistent with this approach to expert evidence, the scheduling order entered for this specific bellwether case does *not* place any limitations on the subject matter of the parties’ experts. (*See* ECF 2982.)

Tr. 19:2-20:11, ECF 1848 (providing the timeframe and format of the MDL *Daubert* hearings).)

⁸ Notably, the case-specific nature of general causation in a personal injury case is the reason why Judge Kugler prioritized trying “a third-party payor case” over one involving personal injuries. (*See* Feb. 28, 2022 Hr’g Tr. 41:8-12, ECF 1946 (reasoning it would be easier “just to get a jury to say yes or no on the question of general causation” in a third-party payor case).)

Plaintiff clearly had the same understanding of the prior scheduling orders in this litigation when she designated Dr. Sawyer—a new expert who was not a subject of the prior *Daubert* proceedings—to evaluate the epidemiological literature, perform a Bradford Hill analysis and opine that “NDMA is a potent probable human carcinogen,” relying in part on Mansouri 2022. (Sawyer Rep. at 39-41, 79.) Although Dr. Sawyer testified at his deposition that he does not know if he is actually providing a general causation opinion in this case (Sawyer 5/1/2025 Dep. 54:2-9 (Rose Decl. Ex. 3); *id.* 101:15-21), his report could not be clearer. And while Plaintiff’s counsel tried to disclaim Dr. Sawyer’s general causation opinion on redirect (Sawyer 5/2/2025 Dep. 161:5-6 (Rose Decl. Ex. 4)), that was notably after Dr. Sawyer was exposed for relying on numerous fabricated scientific articles (*id.* 72:13-17).

In short, there was no order barring new general causation experts for the *Roberts* trial, and Dr. Diette rebutted the opinions of Dr. Sawyer, whose report clearly offers a general cause opinion. For this reason alone, Plaintiff’s motion should be denied.

II. ANY “UNTIMELY” DISCLOSURE WAS SUBSTANTIALLY JUSTIFIED AND HARMLESS.

Plaintiff’s motion would also fail even if Dr. Diette’s report were deemed untimely. Under Rule 37(c)(1), a party that fails to timely disclose expert evidence is not precluded from using the expert where “the failure was substantially justified

or is harmless.” Fed. R. Civ. P. 37(c)(1); *see also ABB Air Preheater*, 167 F.R.D. at 671 (“[T]he Rule vests courts with discretion in its provision that no sanction should be imposed if there was substantial justification for the non-disclosure, or if the non-disclosure was harmless.”). In evaluating this standard, the Third Circuit considers the following factors: “(1) the prejudice or surprise to a party against whom evidence is offered; (2) the ability to cure that prejudice; (3) the likelihood of disruption to trial; (4) the bad faith or willfulness of the party who did not comply with the disclosure rules; and (5) the importance of the evidence to the proffering party’s case.” *Ly Berditchev Corp. v. Truss Cosms. Corp.*, No. 2:22-CV-04242 (BRM) (CLW), 2025 WL 303993, at *6 (D.N.J. Jan. 27, 2025). Here, each of these factors weighs against exclusion of Dr. Diette’s opinions.

Plaintiff Has Not Demonstrated Bad Faith. “The exclusion of critical evidence is an ‘extreme’ sanction, not normally to be imposed absent a showing of willful deception or ‘flagrant disregard’ of a court order by the proponent of the evidence.” *Bayer HealthCare LLC v. Baxalta Inc.*, No. 16-CV-1122-RGA, 2019 WL 297039, at *1 (D. Del. Jan. 22, 2019). Plaintiff does not even address the Third Circuit’s culpability standard.⁹ Rather, at most, she claims that Dr. Diette lacks

⁹ Plaintiff primarily relies on inapposite cases from outside this circuit that do not “consider bad faith as a separate factor in [the] exclusion analysis[.]” *S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 597-98 (4th Cir. 2003) (cited in Pl.’s Br. at 12-15) (explaining that “other circuits interpreting Rule 37(c)(1)

“justification” because there is no “newly discovered evidence or changed circumstances.” (Pl.’s Br. at 16.) But that is false. Plaintiff herself designated new general causation evidence from a new witness who addresses new scientific developments, and Dr. Diette directly responds to that general causation evidence. Even if both parties somehow misconstrued Judge Kugler’s prior scheduling orders, there is simply “no basis on which to conclude that [Defendants] *deliberately* failed to comply with” them. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 793 (3d Cir. 1994) (emphasis added); *see also TQ Delta, LLC v. 2Wire, Inc.*, No. CV 13-1835-RGA, 2019 WL 1529952, at *2 (D. Del. Apr. 9, 2019) (exclusion was not proper because “it was . . . logical for Defendant to believe that it could undertake a more streamlined review of the specific source code identified in the initial reports at a later date”).

Additionally, Defendants are entitled to respond to Plaintiff’s expert evidence, as Dr. Diette does here. While Plaintiff disclaimed Dr. Sawyer’s general causation opinions after Dr. Diette rebutted them (*see, e.g.*, Sawyer 5/1/2025 Dep. 54:2-9), Plaintiff’s “tactical decision” to withdraw Dr. Sawyer as a general causation expert does not entitle her to “control[Defendants’] expert choices.” *In re Puda Coal Sec. Inc., Litig.*, 30 F. Supp. 3d 230, 256 (S.D.N.Y. 2014) (rejecting argument that

apply . . . bad faith as a consideration,” but the Fourth Circuit does not “consider bad faith as a separate factor in [the] exclusion analysis”).

rebuttal expert should be excluded where plaintiffs “chose to withdraw their accounting expert on the same topics” as “misguided” because such a rule “would grant plaintiff a unilateral veto right over the type of proof the [defendants] may offer in their own defense”), *aff’d sub nom. Querub v. Hong Kong*, 649 F. App’x 55 (2d Cir. 2016).

Dr. Diette’s Expert Opinions Are Vitally Important. Plaintiff does not dispute that Dr. Diette’s case-specific general causation opinions are “important” to Plaintiff’s case. (*See generally* Pl.’s Br. at 13-15.) Rather, Plaintiff claims that “[i]mportance of the evidence cannot override the enforcement of local rules and scheduling orders.” (Pl.’s Br. at 15 (citing *S. States*, 318 F.3d at 598).) But as already discussed, the designation of Dr. Diette as an expert is fully consistent with those rules and orders. In any event, *Southern States* does not elaborate on the importance factor (much less state what Plaintiff claims it says), *see S. States*, 318 F.3d at 598, while other courts have made clear that it “was ‘intended’ to mitigate *against* exclusion,” *Ishee v. Fed. Nat’l Mortg. Ass’n*, No. 2:13-CV-234-KS-MTP, 2014 WL 11456486, at *1 (S.D. Miss. Dec. 11, 2014) (emphasis added). This aligns with the Third Circuit’s “distinct aversion to the exclusion of *important* testimony absent evidence of extreme neglect or bad faith on the part of the proponent of the testimony.” *ABB Air Preheater*, 167 F.R.D. at 671, 673 (emphasis added). Because it is undisputed that Dr. Diette’s case-specific general causation opinion is important,

this factor clearly weighs strongly against exclusion.

Dr. Diette's Opinions Will Not Disrupt Trial. Plaintiff claims that "allowing Dr. Diette's report and testimony would significantly disrupt the progress of this MDL, and delay efforts to have Mr. Roberts' case ready for trial by September." (Pl.'s Br. at 15.) But Plaintiff has already deposed Dr. Diette and questioned him about the bases of his causation opinions in this case.¹⁰ There is thus no basis for any claimed "delays." Rather, it is clear that Plaintiff's counsel has decided their trial presentation will be stronger if they dump Dr. Sawyer's causation opinion in exchange for eliminating Dr. Diette from Defendants' witness lineup. That sort of strategic maneuver is not a legitimate basis to strike an expert. Because Plaintiff has not demonstrated that Dr. Diette's report will "disrupt preparation for the trial[]," this factor "weigh[s] against exclusion," too. *TQ Delta*, 2019 WL 1529952, at *2.

Plaintiff Has Not Been Surprised Or Prejudiced. Plaintiff contends that Dr. Diette's expert opinions "come[] as a complete surprise" (Pl.'s Br. at 16-17), but that, too, is disingenuous for many of the same reasons. As explained in detail above, Dr. Diette's report responds directly to Dr. Sawyer's review of the epidemiologic literature (including Mansouri 2020) and attempt at a Bradford Hill analysis.

¹⁰ Plaintiff's claim that Dr. Diette's opinions will "delay the resolution of both class and individual claims" in other cases in the MDL (Pl.'s Br. at 15), is frivolous. The report Plaintiff seeks to exclude addresses the general causation question posed by Mr. Roberts' particular case and is being used for purposes of this case.

Plaintiff cannot manufacture a claim of surprise by now retracting Dr. Sawyer's flawed opinions.

The handful of cases that Plaintiff claims excluded expert testimony “[i]n the MDL context” (Pl.’s Br. at 11), are inapposite. For example, in *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483 (E.D. Pa. 2016) (cited in Pl.’s Br. at 11-12, 15), *aff’d*, 858 F.3d 787 (3d Cir. 2017), the court precluded the plaintiffs from resurrecting an ***already-excluded*** general causation opinion, while allowing “supplement[ation]” of opinions previously held to be admissible. *Id.* at 494. The other cited cases did not involve MDL proceedings and prohibited late supplementation of expert testimony based on unique facts not present here. *See In re C.F. Bean LLC*, 841 F.3d 365, 371 (5th Cir. 2016) (cited in Pl.’s Br. at 12) (excluding new expert opinions submitted as an exhibit to the opposition to a motion to strike the original expert report submitted more than seven months after the deadline); *S. States*, 318 F.3d at 598 (cited in Pl.’s Br. at 12-15) (excluding late-disclosed “surprise” third supplemental opinion formed at the beginning of trial).

For all of these reasons, any late disclosure was substantially justified and harmless.¹¹

¹¹ Plaintiff devotes three sentences to arguing that Rule 16(f) separately warrants exclusion of Dr. Diette’s expert report as a sanction for failing to comply with a scheduling order. (Pl.’s Br. at 18.) But as set forth above, Dr. Diette’s report was

III. NEW DEVELOPMENTS SEPARATELY WARRANT RECONSIDERATION OF ANY PRIOR SCHEDULING ORDERS.

Finally, even assuming Dr. Diette's testimony were somehow untimely, unjustified, and prejudicial under Judge Kugler's prior deadlines, those orders should be reconsidered in light of intervening scientific developments. "As medicine and science continue to advance, so does our understanding about the causes of diseases When the evidence presented differs [from a prior case], a different result is also plausible." *Bean-Sasser v. Sec'y of Health & Hum. Servs.*, 127 Fed. Cl. 161, 167 (2016). Courts have applied this principle in reopening prior *Daubert* proceedings and taking a fresh look at evidence previously deemed admissible based on the current state of the science. Text Order, *In re Talcum Powder Prods. Liab. Litig.*, No. 16-md-2738 (D.N.J. Mar. 27, 2024), ECF No. 30260 (recognizing "the recent changes to Federal Rule of Evidence 702[] [and] the emergence of new relevant science" warranted revisiting expert reports on, *inter alia*, general causation).

submitted in full compliance with the scheduling order entered in Mr. Roberts' case; accordingly, there has been no violation of a scheduling order to justify Rule 16(f) sanctions. *See Ohio Farmers Ins. Co. v. Burch*, No. 2:21-CV-2546, 2021 WL 5782097, at *7 (S.D. Ohio Dec. 6, 2021) (declining to issue sanctions pursuant to Rule 16(f) where defendant "did not violate" the "pretrial order"). Moreover, because courts have analyzed Rule 16(f) sanctions using the same factors as Rule 37(c), *Ward v. Barnes*, No. 05-1850 (JBS), 2008 WL 11510027, at *3 (D.N.J. June 27, 2008), sanctions are separately unwarranted for all the reasons set forth above.

That same principle necessarily supports the far more modest request being made here, which is not to reopen the prior *Daubert* proceedings, but rather to permit Defendants an opportunity to present a new expert who addresses the relevant general causation question according to the current state of the science. As previously discussed, Mansouri 2022—which was decided after the original global general causation deadlines had passed and Judge Kugler issued his *Daubert* ruling—concluded that “[m]ore research is needed” to “establish clinically relevant causality.”¹² This study is clearly relevant to the issue of general causation, as laid bare by Dr. Sawyer’s own three-page write-up of it in his report. (Sawyer Rep. at 39-41.) And permitting Dr. Diette to discuss that study against the broader backdrop of the scientific landscape would simply effectuate Defendants’ right to put on a proper defense.

In short, and at a minimum, Plaintiff’s reading of Judge Kugler’s prior scheduling orders should yield to scientific developments that have arisen since those original deadlines were imposed.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiff’s motion to exclude Dr. Gregory Diette’s report as untimely.

¹² Mansouri 2022 at 12.

Dated: June 26, 2025

Respectfully submitted,

/s/ Jessica Davidson

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 26, 2025, a true and correct copy of the foregoing document was served upon counsel of record via operation of the Court's electronic filing system.

Dated: June 26, 2025

Respectfully submitted,

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